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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,892

07/20/2004

Shigeru Hiramoto

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WENDEROTH, LIND & PONACK, L.L.P.  
2033 K STREET N. W.  
SUITE 800  
WASHINGTON, DC 20006-1021

EXAMINER
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MI, QIUWEN

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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07/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,892	<b>Applicant(s)</b> HIRAMOTO ET AL.	
	<b>Examiner</b> Qiuwen Mi	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's amendment in the reply filed on 5/18/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/18/2007 has been entered.

### **Claims Pending**

Claims 1-14 are cancelled. Claims 15-21 are pending. Claims 15-21 are examined on the merits.

### **Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The phrase "capable of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention, in the instance case, it is not clear whether the substance eradicates *Helicobacter pylori* or not. See MPEP § 2173.05(d).

### **Claim Rejections –35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19 are rejected under 35 USC § 102 (b) as being anticipated by Kim et al (US 6,627,238).

Kim et al (US 6,627,238) teach a browning reaction that contains sugars such as glucose, fructose, galactose, lactose, and free amino groups from proteins of microorganisms (buttermilk, cream cheese) (col 2, lines 4-10) occurs in foods heated by microwave, food containing a dough crust heated in a conventional oven, and food to be baked (col 1, lines 30-35; col 2, lines 50-55). The claims read on any subject that consumes that food and drinks water (an inhibitor of gastric acid secretion).

As evidenced by Shimazake et al (US 4,013,800), 20 g monosodium L-glutamate, 10 g aspartic acid, 30 g xylose in 300 ml water yield 60 g of a Maillard reaction (the same as browning reaction) product, therefore the yield of browning reaction product is about 16.7%.

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Although the sugar, protein, and reaction condition may vary in each individual reaction, more than 0.5% of browning reaction product is easy to meet.

Therefore, the reference is deemed to anticipate the instant claim above.

### Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,329,002) in view of Kim et al (US 6,627,238), and further in view of Kodama et al (US 2001/0044120).

Kim et al (US 6,329,002) teach a method of inhibiting infection from *Helicobacter pylori* with nutritional food (see Title, Abstract), said method comprising administering to a human nutritional food (claim 8) such as buttermilk, cream cheese etc (claim 12).

Kim et al (US 6,329,002) do not teach using more than 0.5% product of a browning reaction, or an inhibitor of gastric acid secretion to inhibit *Helicobacter pylori*.

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As evidenced by Kim et al (US 6,627,238), browning reaction that contains sugars such as glucose, fructose, galactose, lactose, and free amino groups from proteins of microorganisms (buttermilk, cream cheese) (col 2, lines 4-10) occurs in foods heated by microwave, food containing a dough crust heated in a conventional oven, and food to be baked (col 1, lines 30-35; col 2, lines 50-55).

Kodama et al teach inhibiting *Helicobacter pylori* with glycoprotein isolated from milk, dairy products, and meat products, and an inhibitor of gastric acid secretion (see Title, Abstract, p0034, p0044).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use product of brown reaction of Kim et al (US 6,627,238) and the inhibitor of gastric acid secretion to inhibit the infection from *Helicobacter pylori* for the following reasons.

It is clear from Kim et al (US 6,627,238) that baked food or microwaved food containing sugar, milk (protein), and cheese (protein) undergoes browning reaction, and thus contains the product of browning reaction, therefore when Kim et al (US 6,329,002) inhibit infection from *Helicobacter pylori* with baked or microwaved nutritional food containing buttermilk, cream cheese, it actually uses the product of a browning reaction to inhibit infection from *Helicobacter pylori*.

It is also clear from Kodama et al that the glycoprotein isolated from milk, dairy products and meat product is effective in inhibiting *Helicobacter pylori* , therefore when consuming

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nutritional food such as buttermilk, cream cheese of Kim et al (US 6,329,002), the glycoprotein contained in buttermilk, cream cheese (dairy products) is inhibiting *Helicobacter pylori*. In addition, since Kodama et al teach that the combination of the glycoprotein and the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori* (p0044), and since both of the inventions yielded beneficial results in inhibiting *Helicobacter pylori*, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**MICHAEL MELLER**  
**PRIMARY EXAMINER**